IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stephen Pacetti		Examiner: Ho, Uyen T	
Serial No.	09/997,390	Art Unit:	3731
Filed:	November 30, 2001		
Title:	Apparatus and Method For Coating Implantable Devices		

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Commissioner for Patents
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Brief Overview of the File History

The above-identified application was filed on November 30, 2001. It has been pending before the patent office for about 4 years and 7 months. A restriction requirement was issued on December 10, 2003, requesting the Applicant to elect between claims 1-8, claims 9-13, and claims 14-18. Applicant elected claims 1-8, claim 1 being the independent claim. Claim 1 recited, inter alia,

> modifying the ratio of the first ingredient with respect to the second ingredient in the coating formulation **as the coating formulation is being applied to the stent**. (emphasis added)

On January 15, 2004, the Examiner issued the first office action on the claim's merits. The Examiner indicated that U.S. Patent No. 5,464,650 to Berg et al. ("Berg") anticipated the claims under 35 USC § 102(b). The Examiner failed to provide any basis whatsoever as to how the claimed elements were taught by Berg and the office action was significantly below the threshold requirement of the patent office.

Applicant responded to the office action, indicating that Berg simply taught a variation in drug-to-polymer ratio in multiple layers of the coating. In other words, Berg teaches that a first layer is deposited having a drug-to-polymer ratio of A:B; the layer is

then dried; next, a second layer is deposited having a drug-to-polymer ratio of C:D; and then the second layer is dried. Applicant pointed out to the Examiner that the teaching of Berg is not equivalent to modifying "the ratio of the first ingredient with respect to the second ingredient in the coating formulation **as the coating formulation is being applied to the stent.**"

Applicant also added new claims in the response including claim 23, which recites, inter alia:

> modifying the ratios of the ingredients with respect to each other in the coating formulation **while the coating formulation is being applied to the device**. (emphasis added)

Much to the surprise of the Applicant, the Examiner issued another restriction requirement between claims 1 (above) and 23 (immediately above). The Examiner asserted that claim 1 is limited to two ingredients while claim 23 is limited to three ingredients; therefore, the inventions are different. The Examiner further limited the scope of the invention by requesting the Applicant to elect a single species.

Applicant challenged the restriction, indicated that claim 1 is an open ended claim (reciting "comprising") and therefore not limited to just two ingredients. The Examiner kindly agreed and withdrew the restriction requirement between claims 1 and 23; however, the species requirement was maintained.

On October 8, 2004, the Examiner issued another office action, now arguing that the claims are deemed obvious under (1) Berg in combination with De Scheerder at al. (U.S. Patent No. 6,572, 651); and (2) Tuch (U.S. Patent No. 5,624,411) in view of De Scheerder et al.

Applicant responded in the office action response dated January 10, 2005, again, indicating that the combination of all of the references cited by the Examiner failed to teach the underlined claimed language indicate above. More particularly, the Examiner referred to column 2, lines 47-66 of the secondary reference in support of her position. However, there was absolutely nothing in column 2, lines 47-66 of De Scheerder that even remotely resembled the claimed language.

Next, the Examiner issued yet another restriction requirement, requesting the Applicant to even further limit the invention. In essence, the Examiner forced the Applicant to limit the invention to one, minute, infinitesimal embodiment even though there was absolutely no unreasonable searching and examining burden on the Examiner. Aside from being unreasonably limited by restriction requirements throughout the prosecution of this matter, this last restriction requirement was deluged with errors that had to be pointed out to the Examiner. For example, The Examiner failed to include claim 34 in the restriction requirement. Additionally, the Examiner restricted an already non-elected claim set.

On August 24, 2005, the Examiner withdrew the last art-based rejection and issued a new one. The Examiner's position in this office action was that the claims are obvious over Ding (U.S. Patent No. 5,980,972) in view of Berg. Again, as was done previously, the Examiner simply concluded that the claim process was an obvious modification of these two references to control the release of the drug.

The Applicant conducted an Examiner interview. For the sake of moving this case forward, the Applicant agreed to amend the claims as recited in the office action response dated January 17, 2006. Claim 1 was further clarified to recite that the modification of the coating formulation occurs "while to coating formulation is being discharged out from the coating dispenser and onto the stent. Claim 34 was further amended for clarity to recite "wherein the modification occurs without interrupting the application of the coating formulation onto the device from a coating dispenser."

Despite this amendment, the Examiner issues yet another rejection. In the office action dated April 5, 2006, the Examiner now admitted that although the combination of Ding and Berg fails to teach what has been claimed, it is well know in the art to coat stents in this manner. There is nothing in the patent office's record in support of this position.

Remarks Presented

Applicant, with all due respect, submit that despite being bombarded by multiple restriction of group as well as species throughout the prosecution of this application,

which in essence has narrowed the scope of the Examiner's search to the most minute embodiment of this application, the Examiner, through four office actions, has failed to provide a reference that is even remotely on point.

As indicated by the last office action, the best that the Examiner could do is to say that although the claimed limitations are not taught by the combination of the references, one of ordinary skill in the art would simply know to coat a medical device or stent by the claimed process. The Examiner has simply concluded that it would be a matter of design choice to modify the ratio as the formulation is being applied since the Applicant failed to indicate any problems that are resolved or any particular purpose that the claimed process serves.

First, since the Examiner on the record has indicated that the combination of the references fails to teach what has been claimed, this admission alone should be sufficient for allowance of the claims.

Second, the Examiner, on almost each occasion has fallen well short of what is required for an adequate office action. As is typified in the last office action, Applicant is simply provided with a conclusion, without any support or reasoning, that the claims are obvious, even though the references do not teach what is claimed.

Third, the Examiner's contention, which is the only basis of the rejection -- namely, that the Applicant has failed to provide the problems solved or purposes served -- is not only without legal merit, but also a factual error. The law does not require the applicant to provide for problems that are solved or purposes which are served. Even if this was the case, Applicant has provided for problems that are solved in the specification. For example, as discussed in the specification, the process of the present invention allows for a biocompatible polymer to be used with an incompatible, structural or adhesive polymer. By gradually transitioning the ratios of the two polymers during the coating process, the structural polymer could be initially used in higher ratios for better adhesion to the surface of the stent while the more biocompatible polymer could be used in higher ratios in the end of the process for surface contact with tissues and blood. A gradual transition in ratios minimizes or eliminates interfacial surface boundaries of traditional layering constructs -- such as those disclosed in the art cited by the examiner --

which can delaminate from one another and create emboli, disturb blood flow, and provide a surface that can cause thrombosis, for example.

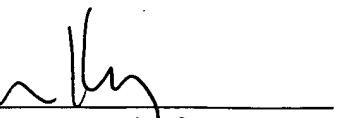
Moreover, as indicated in the specification, the layering techniques -- such as those disclosed by Berg -- can cause drug extraction from the lower layers during the deposition of the upper layers (e.g., by solvent extraction). This results in unpredictable manufacturing inconsistencies with respect to the release rate profile of the drug. More significantly, it can result in a "burst" release of the drug since the drug can be extracted to the outer layers of the polymer coating. As indicated in the present specification, a gradual change in the polymer-to-drug ratio is intended to minimize or eliminate these problems. These are issues that are not even remotely discussed by the references disclosed by the Examiner. Yet, the Examiner, without any support whatsoever, deems the claims as being obvious, even though an admission has been made that the combination of the references does not disclose all of the claimed elements.

Fourth, to-date, not one reference cited by the Examiner has disclosed "modifying the ratio of the first ingredient with respect to the second ingredient in the coating formulation while the coating formulation is being discharged out from the coating dispenser and onto the stent." Applicant respectfully submits that the Examiner's position throughout the prosecution of this application have been well short of the standards required by the patent office.

Applicant requests removal of the rejection and issuance of a notice of allowance.

Date: July 5, 2006

Respectfully submitted,



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